K100391 #1/6

510(k) Summary

(As required by 21 CFR §807.92 and 21 CFR §807.93)

SEP 2 9 2010

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration Number: 1818910
MANUFACTURER:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration Number: 1818910
510(K) CONTACT:	Dawn Sinclair, MA Regulatory Affairs Associate Telephone: (574) 372-5023 Facsimile: (574) 371-4987 Electronic Mail: Dsincla3@its.jnj.com
DATE PREPARED:	May 11, 2010
PROPRIETARY NAME(S):	DePuy Universal Gription™ TF Cones (Knee) DePuy Gription™ TF Acetabular Augment System (Hip)
COMMON NAME(S):	Cone Components (Knee) Acetabular Augments, Buttresses, Shims (Hips)
CLASSIFICATION(S):	**KNEE** Class II per 21 CFR § 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis Class II per 21 CFR § 888.3510 Knee joint femorotibial metal/polymer Constrained cemented prosthesis

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HIP

Class II per 21 CFR § 888.3358
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Class II per 21 CFR§ 888.3350
Hip joint metal/polymer semi-constrained cemented prosthesis

Class II per 21 CFR § 888.3330
Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Class II per 21 CFR § 888.3353
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

DEVICE PRODUCT CODE(S):

87JWH, 87KRO (Knee)

87LPH, 87KWA, 87JDI,
87LZO (Hip)

SUBSTANTIALLY EQUIVALENT DEVICE(S):

KNEE

Trabecular Metal™ Tibial Cone Augments and Trabecular Metal™ Femoral Cone Augments, K053340
Trabecular Metal™ Metal Femoral Cone Augments, K051756

HIP

Trabecular Metal™ Acetabular Augments, K061067
Trabecular Metal™ Acetabular Augments, K042871
Biomet Porous Titanium Acetabular Augments, K052888

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DEVICE DESCRIPTION: KNEE

The DePuy Universal Gription TF Cone component is manufactured from Commercially Pure (CP) Titanium Powder conforming to ASTM Specification F-1580. The Gription TF Cone is an optional component intended to provide improved fit of the femoral or tibial prosthesis where the metaphyseal bone in the distal femur or proximal tibia is either absent or of poor quality. The Gription TF Cone component consists of a conical CP Titanium porous structure with a general cone shaped geometry tapering from the surface nearest the joint line to a smaller dimension internal to the metaphysis. The hollow cone shape made of this porous material provides a porous structure to interface with the native bone and an internal geometry that allows for cement adhesion between the cone and the mating implant (either tibial or femoral component). The Gription TF Cone component is affixed to the mating tibial base or femoral component using bone cement. The cones are intended for fixation as an assembled construct in either the proximal tibia or distal femur, with or without bone cement, in cases of severe bone loss.

There are eight component sizes: 45x15, 53x15, 53 mm stepped LT, 53 mm stepped RT, 61x15, 61x30, 61 mm stepped LT, and 61 mm stepped RT. The larger dimension represents the widest M/L points of the cones and the second dimension represents the depth of the implant. The stepped cones will have two depth levels that are split halfway across the part; these depths are 15 and 30 mm. These stepped cones are labeled Left or Right indicating the side with the shorter 15 mm dimension. The narrow end of the cone provides an opening with a minimum dimension across of 24.5 mm to allow for DePuy stems of all diameters to pass through the hole without interfering with the cone.

DEVICE DESCRIPTION: HIP

The DePuy Gription TF Acetabular Augment System provides an alternative to structural allograft for augmenting moderate to large-sized segmental acetabular defects encountered in acetabular reconstruction. The Gription TF implants are manufactured from Commercially Pure (CP) Titanium powder conforming to ASTM Specification F-1580. The Acetabular Augment implants are used to fill an acetabular defect giving the acetabular shell support where bone is missing or inadequate. The Augment has an inside diameter designed to mate with the outside diameter of the Pinnacle Acetabular Shell system. The porous Gription TF acetabular augment is affixed to the mating acetabular cup using bone cement or mechanical fixation. The Acetabular Augments incorporate screw holes that allow for the use of bone screws for adjunct fixation of the acetabular component to the native bone. The Acetabular Augments also incorporate a slot feature used to mechanically attach the augment to the acetabular shell with or without the use of bone cement. The assembled porous titanium augment/acetabular construct is intended for cemented or cementless use.

The Gription TF Acetabular Augments come in four thicknesses (10, 15, 20 and 30 mm), and six different outside diameters (50, 54, 58, 62, 66 and 70 mm). The 10 mm thick Augments have two holes for pin instrument placement as well as four total screw holes (2 on the flat, 2 in the ID) for adjunct fixation to the host bone. The 15, 20 and 30 mm thick augments have six total screw holes (4 on the flat, 2 in the ID) for adjunct fixation to the host bone. All augments have two

screw holes on the ID of the Acetabular Augments that were designed to travel perpendicular to the other screw holes for added stability when attached to the host bone. All of the Acetabular Augments have cutouts for clearance when other screws are used in the acetabular shell. Each Augment implant has an inside diameter designed to mate with the outside diameter of the Pinnacle Acetabular Shell system. The Augment implants can be cemented to the shell, or mechanically fixated by threading a 6.5 mm Cancellous bone screw through the shell into the slot in the Augment.

The DePuy Gription TF Acetabular Buttress Augments are designed to support the acetabular shell in a manner similar to the augment implants; however, the Buttress implant spans the defect in the acetabulum. The Gription TF Acetabular Buttress is affixed to the mating acetabular cup using bone cement. The assembled porous titanium buttress/acetabular construct is intended for cemented or cementless use. The Buttress implant is fixated to the host bone by 5.5 mm tapered head locking screws, as well as 6.5 mm Cancellous bone screws using pre-drilled screw holes in the Buttress Augment implant.

The Gription TF Buttress implants come in three sizes (56, 62 and 68 mm) and three configurations (Left, Right and Neutral). Each Buttress implant has six total screw holes; two are for use with 6.5 mm Cancellous bone screws and four are for use with 5.5 mm locking or non-locking Cancellous bone screws. Each Buttress implant has a spherical inside diameter which is designed to mate with the acetabular shell's outside diameter. The Gription TF Buttress implants were designed to have a curved, tapered top side to facilitate implanting under soft tissue.

The Gription TF Shim implants are designed to mate with the Buttress implant to raise or support the end of the Buttress when pelvic geometries are not flat. The porous Gription TF Shim is affixed to the mating Buttress using bone cement. The assembled porous titanium buttress/shim construct is intended for cemented or cementless use. The Shim implant has clearance holes for Buttress screw adjunct fixation.

The Gription TF Shim implants come in three different configurations: 5-degree, 10-degree and 15-degree shapes. The Shim implants have four clearance holes for the 5.5 mm tapered head locking screws coming from the Buttress implant. The Gription TF Shim implants can be oriented in any direction to fit the bony geometry of the patient.

Intended Use: Knee

The DePuy Universal Gription TF Cones are intended for use in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention.

Intended Use: Hip

The DePuy Gription TF Acetabular Augment System is intended to provide the orthopaedic surgeon with a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies.

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Indications for Use: Knee

The DePuy Universal Gription TF Cones are intended for use with the P.F.C. Modular Knee, P.F.C. Sigma Knee, Sigma TC3 Revision Knee, and S-ROM Tibial Tray in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention.

The porous Gription TF titanium cone is affixed to the mating tibial or femoral component using bone cement. After attachment, the cones are intended for fixation as an assembled construct into either the proximal tibia or distal femur, with or without bone cement.

Indications for Use: Hip

The DePuy Gription TF Acetabular Augments, Buttresses and Shims are indicated for use with the Pinnacle® Acetabular Cup System, the Pinnacle® Bantam Acetabular Cup System and the Pinnacle® Revision Acetabular Cup System for total hip replacement in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The porous Gription TF titanium acetabular augment is affixed to the mating acetabular cup using bone cement or mechanical screw fixation. The assembled augment/acetabular cup construct is intended for **cemented** or **cementless** use.

The porous Gription TF titanium shim is affixed to the mating buttress using bone cement. This porous Gription TF titanium buttress is affixed to the mating acetabular cup using bone cement. The assembled buttress/acetabular cup construct is intended for **cemented** or **cementless** use.

Summary of Technologies/Substantial Equivalence: Knee

The substantial equivalence of the DePuy Universal Gription TF Cones is shown by the similarity in intended use, indications for use, materials and performance to the cited predicate devices and does not present any new issues of safety or effectiveness. The DePuy Universal Gription TF Cones and the legally marketed predicate devices are composed of a highly porous material; the cone is tapered, and; the center of each cone is hollow to allow passage of the stem through the center of the cone into the femoral or tibial canal. The DePuy Universal Gription TF Cones and the Trabecular Metal Femoral Cone Augments both offer an optional metaphyseal component for use with femoral total knee prosthesis components.

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Summary of Technologies/Substantial Equivalence: Hip

The substantial equivalence of the DePuy Gription TF Acetabular Augment System is shown by the similarity in intended use, indications for use, materials and performance to the predicate devices and does not present any new issues of safety or effectiveness. The DePuy Gription TF Acetabular System and the legally marketed predicate devices are composed entirely of a highly porous material and have similar technological and geometric features. The DePuy Gription TF Acetabular System and the predicate devices are all intended to provide the orthopaedic surgeon with a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies. The DePuy Gription TF Acetabular System and the predicate devices incorporate screw holes that allow for the use of bone screws for adjunct fixation.

Non-clinical Testing: Knee and Hip

Non-clinical testing was provided, including testing outlined in the FDA "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement (28 April 1994)". The following testing was conducted: Animal Testing, Augment Pull-Off and Shear-Off Testing, Screw Push-Out Testing, Screw Pull-Off and Shear-Off Testing, Shear Fatigue Testing per ASTM F1044, Static Shear Testing, Abrasion Strength Testing, Compression Fatigue Strength Testing, Cement Interfacial Tensile and Shear Testing, and Compression Fatigue Strength Testing. This testing and an evaluation of the device design and geometry demonstrated that the DePuy Universal Gription TF Cones and DePuy Gription TF Acetabular Augment System met performance requirements and are as safe and effective as their predicates. This information and testing data formed the basis for a determination of substantial equivalence. The results demonstrated that the device was functional within its intended use.

Clinical Testing:

None provided as a basis for substantial equivalence.

Conclusion:

The DePuy Universal Gription TF Cones and DePuy Gription TF Acetabular Augment System are substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Orthopaedics, Inc.
% Ms. Dawn Sinclair
Regulatory Affairs Associate
700 Orthopaedic Drive
Warsaw, Indiana 46581

SEP 2 9 2010

Re: K100391
Trade/Device Name: DePuy Universal Gription™ TF Cones & Acetabular Augment System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, KRO, KWA, LPH, JDI, LZO
Dated: August 2, 2010
Received: August 4, 2010

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Dap Dir

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510 (k) Number (if known): K100391

Device Name: DePuy Universal Griptionᵀᴹ TF Cones

Indications for Use:

The DePuy Universal Griptionᵀᴹ TF Cones are intended for use with the P.F.C.® Modular Knee, P.F.C.® Sigma® Knee, Sigma® TC3 Revision Knee, and S-ROM® Tibial Tray in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention.

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Device Name: DePuy Griptionᵀᴹ TF Acetabular Augment System

Indications for Use:

The DePuy Gription TF Acetabular Augments, Buttresses and Shims are indicated for use with the Pinnacle® Acetabular Cup System, the Pinnacle® Bantam Acetabular Cup System and the Pinnacle® Revision Acetabular Cup System for total hip replacement in the following conditions:

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Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100391